

**Virginia Division of Consolidated Laboratory Services
Virginia Environmental Laboratory Accreditation Program**

FREQUENTLY ASKED QUESTIONS

PROFICIENCY TESTING (1VAC30-45 and 1VAC30-46)

Updated November 2, 2022

REFER TO 1VAC30-45 OR 1VAC30-46 AND THE 2016 TNI STANDARD FOR ALL REQUIREMENTS FOR PROFICIENCY TESTING. THIS DOCUMENT IS NOT INTENDED TO REPLACE THE REGULATION AND STANDARD.

Why is proficiency testing important?

Satisfactory and continuing proficiency testing (PT) is a **critical component** of the certification or accreditation process under the Virginia Environmental Laboratory Accreditation Program (VELAP). Proficiency testing is required by regulation to demonstrate a laboratory's ability to satisfactorily perform tests for which it is certified or accredited.

Where are PT requirements described in the regulation?

For Chapter 45 Certification: 1VAC30-45, Part II, Article 3 (1VAC30-45-500 through 1VAC30-45-520)

For Chapter 46 Accreditation: 1VAC30-46-200 A, which incorporates by reference 2016 TNI Volume 1 Module 1

What is the relationship between Fields of Proficiency Testing and Fields of Certification or Accreditation?

A "Field of Accreditation" (FOA) or a "Field of Certification" (FOC) is a matrix + method + analyte combination for which a laboratory is certified or accredited. The matrices offered under VELAP are non-potable water, solid and chemical materials, drinking water, biological tissue, and air and emissions.

"Field of Proficiency Testing" (FoPT) means the FOC/FOA held by the laboratory for which PTs are required because the analyte has been listed on the TNI FoPT table for the matrix listed in the laboratory's FOC/FOA. Any questions about whether a PT is required for a FOC/FOA can be referred to the VELAP office (Lab_Cert@dgs.virginia.gov).

What are the PT requirements for VELAP certification or accreditation?

- **VELAP certified/accredited laboratories are responsible for meeting all regulatory requirements and should refer to the regulations, in their entirety, for complete PT information.**
- For **Chapter 45** (non-commercial laboratories) certification:
 - The laboratory seeks and maintains certification by participating in **one single blind, single concentration PT study, where available, per calendar year for each Field of Proficiency Testing.** The laboratory is required to perform a PT study prior to September 30 each year.

- The PT study submitted to VELAP to satisfy the initial application requirement must have been performed within 12 months of the application date.
- For **Chapter 46** (commercial laboratories) accreditation:
 - The laboratory participates **in two single blind, single concentration PT studies, where available, per year for each Field of Proficiency Testing** for which the laboratory wishes to seek or maintain accreditation. The laboratory maintains accreditation by successfully completing two PT studies for **each** requested FOA within the most recent three rounds attempted. Successive PTs are completed on an ongoing testing schedule with no longer than seven (7) months separating the analysis dates of the subsequent studies.
 - The PT Studies submitted to VELAP to satisfy the initial application requirements (including a Change in Scope request) must have been performed within 18 months of the application date and the most recent study must have been performed within 6 months of the application date.
 - Once an application (including a Change in Scope request) is submitted, the laboratory must continue to participate in PT studies with no more than seven months between consecutive PT study closing dates from that point on.
 - **NOTE: It is the laboratory's responsibility to establish an ongoing PT schedule to ensure participation in PT studies for the added test(s) at least semi-annually (no more than 7 months apart between consecutive attempts), starting with the most recent PT study submitted with the Change in Scope request. (2016 TNI V1M1 5.1.1.d)**
 - Example 1: A laboratory performs Metals PTs in studies closing on **April 1 / October 1** each year. If the laboratory performs a quick-turnaround study closing on **January 1** to add a new metal to its panel of metals testing, the laboratory may test this new metal **again in the April PT study** and thereafter remain on the April / October schedule for all metals. This approach continually meets the PT requirements for the added test(s) and the tests already held.
 - Example 2: A laboratory adds EPA Method 8260 D to its scope with PT tests closing on **January 1** and **March 1**. The laboratory may select a semi-annual schedule for this new type of testing by performing its next set of PT samples in **a study closing before October 1** and then continuing a semi-annual schedule thereafter.
 - Please reach out to your laboratory's VELAP contact if you need assistance in determining how to manage the PT schedule in keeping with 2016 TNI V1M1 5.1.1.d.
 - When reviewing the validity of consecutive studies, the opening date of the second study must be at least seven calendar days after the closing date of the first study.
 - For the review of consecutive studies, opening and closing dates are defined as follows:
 - **PT Study Opening Date:**
 - **Scheduled PT Study:** The calendar date that a PT sample is first made available to all participants of the study by a PT Provider.
 - **Supplemental PT Study:** The calendar date the PT Provider ships the sample to a laboratory.
 - **PT Study Closing Date:**
 - **Scheduled PT Study:** The calendar date by which all participating laboratories must submit analytical results for a PT sample to a PT Provider.

- **Supplemental PT Study: The calendar date a laboratory submits the results for a PT sample to the PT Provider.**
- Both commercial and non-commercial laboratories seeking a change in scope must meet the PT requirements for initial certification/accreditation for the additional fields of certification or accreditation requested.
- PT samples are handled (i.e., managed, analyzed, reported) in the same manner as real environmental samples utilizing the same staff and methods as used for routine analysis of that analyte (i.e., same procedure, equipment, and facilities).
- When analyzing a PT sample, the laboratory must use the same preparation, calibration, laboratory quality control and acceptance criteria, sequence of analytical steps, number of replicates, and other procedures as used when analyzing routine samples, as described in the laboratory's Standard Operating Procedure.
- Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document for its own records and provide for DCLS both the investigation and the action taken, upon request.
- A laboratory may not send a PT sample or any portion of a PT sample to another lab for any analysis for which it seeks certification or accreditation.
- Laboratory management or staff may not communicate with any individual at another laboratory (including intra-company communication) concerning the PT sample.
- A laboratory may not knowingly receive any PT sample or portion of a PT sample from another laboratory for any analysis for which the sending laboratory seeks certification or accreditation.
- For Chapter 45 Laboratories: When a laboratory has failed to meet the calendar year PT requirements, the PT studies done as "make-up" studies to address the absent (non-participation) studies are not credited toward compliance for the new year.

For example: A laboratory does not participate in PT testing in the 2021 calendar year as required by the regulation. The laboratory performs a PT study in January of 2022 in order to address the reason the laboratory's potential certification suspension. The make-up study does not count towards meeting the PT requirements in calendar year 2022 in this example.

Where can I find a list of the available Fields of Proficiency Testing (FoPT)?

The NELAC Institute (TNI) website maintains a list of available Fields of Proficiency Testing:
<http://www.nelac-institute.org/content/NEPTP/fopt.php>

The TNI website has an option for subscribing to e-mail notifications when updates are made to the FoPT tables. All laboratories are encouraged to subscribe to this notification service and review the FoPT tables periodically for information pertinent to their certifications or accreditations.

There are Fields of Proficiency Testing for the following matrices: drinking water, non-potable water, and solid and chemical materials.

Where can I find a list of approved proficiency test providers?

The NELAC Institute (TNI) website maintains a list of approved PT providers:
<http://www.nelac-institute.org/content/NEPTP/ptproviders.php>

Do I need to perform a PT study if the FoPT corresponding to my accreditation is not on the TNI FoPT table?

No, a Field of Proficiency Testing that is not on the NELAC Institute approved list is not required to be performed for VELAP accreditation or certification. However a NELAC Provider may offer PT samples that have not been approved by NELAP. Although not required to maintain certification or accreditation, successful participation in proficiency studies provides an external validation to a laboratory's internal quality assurance program. For those Fields of Certification or Accreditation where a PT Study is not available by an approved NELAC provider and no proficiency sample was performed, the VELAP assessor may require additional on-site time with data review.

How do laboratories report PT study results to DCLS?

The laboratory communicates the request to the PT provider for results to be directly reported to DCLS / VELAP prior to the closing date of the study, **including studies for initial certification or accreditation**.

The laboratory uses its EPA ID Number when reporting results to the PT Provider. Any questions about EPA ID Numbers can be directed to VELAP at Lab_Cert@dgs.virginia.gov

What steps must laboratories take to ensure successful reporting?

Laboratories are responsible for accurate reporting PT studies in a manner that correlates with the certifications or accreditations held. Laboratories must:

❖ **Ensure a specific match between PT results and laboratory fields of certification/accreditation:**

A PT result must have a specific match between the analytical result and the corresponding FOC/FOA for which the PT sample was analyzed.

Laboratories ensure a specific match between their analytical result for a PT study and their field of certification or accreditation by:

- Ensuring the purchase of the correct PT study matrix to correspond with the FOC/FOA.
- Ensuring accurate reporting of the analyte and matrix to correspond with the FOC/FOA on the laboratory's VELAP certificate.

❖ **Submit a PT result for every applicable field of certification/accreditation:**

It is critical that laboratories ensure complete PT reporting for EVERY FOA held by the laboratory for every PT study, when a PT is required.

- *Note that when a laboratory analyzes a PT sample one time to satisfy the PT requirements for more than one method of the same technology, **the laboratory must REPORT the PT sample result BY EACH ACCREDITED METHOD.***
- For example, if the laboratory performs a series of volatile compounds in non-potable water by EPA 624.1 and also holds accreditation for EPA 8260D in non-potable water, the laboratory **MUST REPORT THE RESULTS BY BOTH EPA 624.1 AND EPA 8260D IN ORDER FOR THE PT DATA TO BE RECORDED IN VELAP RECORDS FOR ALL APPLICABLE FIELDS OF ACCREDITATION.**
- **Failure to report the results to the PT provider for each FOC/FOA may result in the assignment of non-participation failures for the un-reported FOCs/FOAs.**
- For drinking water fields of accreditation, the PT must be analyzed by each accredited method; reporting an analysis for all methods in the same technology is not allowed for drinking water samples. (See Drinking Water PT questions, below.)

❖ **Report PT results down to the specified PTRL:**

PTs for all programs are scored by PT Providers in accordance with the reporting rules described in 2016 TNI Volume 1 Module 1. Laboratories are required to report PT results down to the TNI FoPT analyte+matrix reporting limit designated on the TNI FoPT tables. This PT reporting limit or PTRL is available in the tables located at <http://www.nelac-institute.org/content/NEPTP/fopt.php>.

- The laboratory needs to review all reporting limits against PTRL limits to become aware of which PTs (if any) might possibly have a study result that is lower than the laboratory's typical reporting limits (RL).
- If a PTRL is equal to or higher than the laboratory's RL:
 - The laboratory does not need to make any special accommodations in the testing or reporting of the proficiency sample.
- If a PTRL is lower than the laboratory's RL:
 - The laboratory must modify its normal RL to the PTRL value for the analysis of the PT sample. For this situation the following options are available to the laboratory:
 - The laboratory may report the PT, if needed, as a value lower than the lowest calibration standard. In this situation a qualifier on the reported PT sample is not required. OR,
 - The laboratory may change its typical calibration range when the PT sample is analyzed and use a lower standard that accommodates the PTRL.
- TNI has provided a guidance document on reporting PTs to the PTRL. The document includes numeric examples to illustrate various reporting scenarios and may be helpful for further review on this topic. <https://nelac-institute.org/docs/guidance/21728507.pdf>

How do Chapter 46 laboratories satisfy the requirement for two studies per calendar year?

- To maintain certification, dates of successive proficiency rounds for a given PT Field of Testing **have closing dates no more than seven (7) months apart.**
- **Failure to meet the semiannual schedule is regarded as a failed study. A failure is assigned if more than seven (7) months passes between closing dates of successive studies.**
- Note that for the purposes of evaluating PT timelines, a month is defined as a period of time extending from one date to a corresponding date in the next calendar month. For example, from January 15 until July 15 is six months.

What happens if my instrument is down when it is time to do my PT study, or for some other reason I cannot perform the PT before there has been a 7 month lapse since the closing date of the previous study?

The laboratory has two options:

- Accept the PT failure for the affected Fields of Certification or Accreditation for non-participation, OR
- Before the PT's due date, request voluntary suspension of the certification or accreditation until such time that the lab is able to resume testing. A revised certificate will be issued.
 - To re-instate certification or accreditation and resume this testing, the PT requirement must have been successfully met.

What happens if a laboratory cannot maintain a successful history of PT studies?

- Whenever a laboratory fails a study, it shall determine the cause for the failure and take any necessary corrective action. It shall then document for its own records and provide for DCLS both the investigation and the action taken, upon request.
- For Chapter 46 accreditation, failure of any two out of the most recent three PT studies for a given Field of Certification or Accreditation could result in **withdrawal of accreditation** for the failed fields of testing (See 1VAC30-46 100).
- For Chapter 45 certification, failure to perform annual PT testing as required by the regulation could result in **decertification**.
- To give the laboratory an opportunity to correct this deficiency before decertification or withdrawal of Fields of Certification or Accreditation, DCLS may **suspend** the certification or accreditation for the affected fields of testing for up to six months or the period of certification, whichever is longer.
- DCLS Standard Operating Procedures regarding suspension will give the laboratories an opportunity to restore the PT history before taking final action to suspend failed fields of testing. The laboratory can perform additional PT studies during this window of time provided to the laboratory to meet the regulatory requirements and avoid suspension.
- Suspension cannot exceed six months or the period of certification, whichever is longer. If the laboratory has not successfully restored certification or accreditation during the allowed suspension period, the Field of Certification or Accreditation will be **decertified or withdrawn**.
- **Suspended Fields of Certification or Accreditation may not be analyzed/reported.**
- Certification or accreditation will be restored for FOCs that have been suspended after the laboratory successfully meets regulatory requirements for PT performance.
- Following decertification or withdrawal/revocation, the laboratory must re-apply for those fields of certification and additional fees will be charged in keeping with Change in Scope procedures.

Can a laboratory perform supplemental PT Studies?

- A laboratory may elect to participate in supplemental PT studies when the laboratory desires to add Fields of Proficiency Testing to its scope of certification or accreditation, or when a laboratory fails an initial or continuing PT study and wishes to re-establish its history of successful reporting.
- **There must be at least 7 calendar days from the closing date of one study to the opening date of another study for the same PT field of testing.** Refer to definitions of opening date and closing date provided on page 2.
- Laboratories performing supplemental PT studies are responsible for communicating with the PT provider regarding the laboratory's need for the study when the study is ordered.

Does DCLS accept revised results from the PT provider?

- DCLS does not accept modifications to analysis results submitted after the close of the study.

What are the special requirements applicable to drinking water PT studies?

A PT sample must be successfully analyzed by every accredited method at least once per year to satisfy PT requirements in 40 CFR 141 through 143 for compliance testing under the Safe Drinking Water Act. To simultaneously satisfy both the EPA and the TNI requirements, a laboratory holding drinking water fields of accreditation through 1VAC30-46 must:

- perform proficiency testing continually on a semi-annual basis, and maintain a successful PT history of 2 out of 3 of the most recent PT studies;

- analyze each PT sample by each accreditation method (Note: DCLS requires each accredited drinking water method to be subjected to proficiency testing on a semi-annual basis regardless of the technology.); and
- meet any specialized PT requirements of 40 CFR 141 or TNI, such as:
 - Volatile Organic Compounds (VOCs) – pass 80% per study and additionally pass vinyl chloride [40 CFR 141.24 (f)(17)(i)(B)].
 - Organic Disinfection Byproducts (Haloacetic acids or HAA5) – pass 4 of 5 HAA5s per study [40 CFR 141.131(b)(2)]
 - Total Trihalomethanes (TTHM) – pass 4 of 4 TTHMs per study [40 CFR 141.131(b)(2)]
 - Gamma emitters – pass 5 of 5 gamma emitters per study [TNI Radiochemistry FoPT Table, footnote 6].